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ACTION

Introduced by Mr. Mathias, et.al.

By Mr. MATHIAS (for himself, Mr. ROBERT C. BYRD, Mr. THURMOND, Mr. PERCY, and Mr. DECONCINI):

S. 255. A bill to amend the patent law to restore the term of the patent grant for the period of time that nonpatent regulatory requirements prevent the marketing of a patented product; to the Committee on the Judiciary.

PATENT TERM RESTORATION ACT OF 1981

● Mr. MATHIAS. Mr. President, today I am introducing the Patent Term Restoration Act of 1981. I am especially pleased to note that the distinguished minority leader of the Senate (Mr. ROBERT C. BYRD), the chairman of the Judiciary Committee (Mr. THURMOND), the chairman of the Foreign Relations Committee (Mr. PERCY), and the ranking minority member of the Subcommittee on the Constitution (Mr. DECONCINI) have joined me as cosponsors.

Our bill is designed to encourage American innovation by restoring the effectiveness of the patent system as it affects certain products subject to premarket testing by the Federal Government. I want to make it clear at the outset that our bill will in no way alter our commitment to the public to make sure that new products are safe for public use. But it does correct an inequity. Under current law, the Government grants a 17-year patent and then prohibits the product from being marketed until all tests are completed. During this time, the life of the patent is ticking away, often for many years.

This inequity hits small innovative businesses especially hard. They need the protection that a patent offers in order to protect their new ideas and innovations. These companies cannot afford to lose valuable years of patent coverage while awaiting premarket clearances from Federal regulatory agencies. It has been well documented that small businesses are the most innovative segment of our economy and the most dependable source of new jobs for our workers. Our bill will help these innovative companies provide the new products and jobs that are so desperately needed by the public.

In the past 15 to 20 years, a number of important laws have been enacted requiring that certain products be tested to insure that they are safe for marketing in the areas of public health and the environment. Gradually, as tests have become more and more sophisticated, the time needed to clear th's review has grown. In 1962, for example, it took approximately 2 years and $6 million (or $15 million in 1979) to bring a new medicine from the laboratory to the marketplace.

It now takes, on average, 7 to 10 years and about $70 million to complete this testing period. Thus, it is not uncommon for a drug product to have lost up to one-half of its patent life without having been marketed. Similarly, the Environmental Protection Agency has estimated that the patent life for chemical products has been reduced to about 12 years. This phenomenon, coupled with the inability of many new products to achieve commercial success, discourages innovation—the historic basis of our prosperity.

This adverse impact upon innovation has resulted in fewer new and better products being introduced to the American consumer. For example, from 1955 through 1962, an average of 46 new drugs were introduced annually in the United States; today that average is only 17 new drugs a year, a decline of 63 percent. Similar trends are seen in other areas where the United States was once preeminent. Unless we turn around this trend, we will increase our dependence on foreign technology.

Right now the importation of foreign manufactured goods is the second biggest drain on our economy behind oil imports. While the West Germans and Japanese have redoubled their research and development efforts, many of our own companies have been forced to reduce the level of resources they can devote to research. Strengthening the patent system is one way to encourage them to invest more in R. & D. Our bill will do just that.

As Thomas Jefferson observed when he drafted the United States first patent law in 1793, "ingenuity should receive a liberal encouragement." The 17-year term of our patents was designed under this philosophy; but when our regulatory process effectively cuts this term in half, it should be no surprise that innovation suffers.

If this trend is not reversed, we will continue to fall behind our foreign competitors, who are careful to reward innovation. The real victims of this breakdown are the American people, who are deprived of new products.

The purpose of the present bill is to restore to products subject to premarket review requirements a period equal to the time required for this clearance—up to a maximum of 7 years. If the product does not clear the review, no extension of the patent will be granted. Further, such restoration of the patent will apply only to the specific purpose or use involved in the regulatory approval and not to the entire range of products that might result from the original patent grant.

I expect to conduct hearings on this bill early in the 97th Congress. The new administration wants to increase productivity by encouraging innovation. I urge our colleagues to consider this bill and join us as cosponsors of the Patent Term Restoration Act of 1981.

I ask unanimous consent that the text of the bill and the section-by-section analysis be printed in the RECORD immediately following this statement.

There being no objection, the bill and analysis were ordered to be printed in the RECORD, as follows:

S. 255

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Patent Term Restoration Act of 1981.

SECTION 1. Title 35 of the United States Code, entitled "Patents" is amended by adding the following new section immediately after section 154:

"§ 155. RESTORATION OF PATENT TERM.

"(a)(1) Except as provided in paragraph (2), the term of a patent which encompasses within its scope a product, or a method for using a product, subject to a regulatory review period shall be extended by the amount of time equal to the regulatory review period for such product or method if—

"(A) the owner of record of the patent gives notice to the Commissioner in compliance with the provisions of subsection (b)(1);

"(B) the product or method has been subjected to a regulatory review period pursuant to statute or regulation prior to its commercial marketing or use; and

"(C) the patent to be extended has not expired pror to notice to the Commissioner under subsection (b)(1). The rights derived from any claim or claims of any patent so extended shall be limited in scope during the period of any extension to the product or method subject to the regulatory review period and to the statutory use for which regulatory review was required.

"(2) In no event shall the term of any patent be extended for more than seven years.

"(b)(1) Within ninety days after termination of a regulatory review period, the owner of record of the patent shall notify the Commissioner under oath that the regulatory review period has ended. Such notification shall be in writing and shall:

"(A) identify the Federal statute or regulation under which regulatory review occurred;

"(B) state the dates on which the regulatory review period commenced and ended;

"(C) identify the product and the statutory use for which regulatory review was required;

"(D) state that the regulatory review referred to in subsection (a)(1)(B) has been satisfied; and

"(E) identify the claim or claims of the patent to which the extension is applicable and the length of time of the regulatory review period for which the term of such patent is to be extended.

"(2) Upon receipt of the notice required by paragraph (1), the Commissioner shall promptly (A) publish the information noticed in the Official Gazette of the Patent

and Trademark Office, and (B) issue to the owner of record of the patent a certificate of extension, under seal, stating the fact and length of the extension and identifying the product and the statutory use and the claim or claims to which such extension is applicable. Such certificate shall be recorded in the official file of each patent extended, and such certificate shall be considered as part of the original patent.

"(c) As used in this section:

"(1) The term 'product or a method for using a product' means—any machine, manufacture, composition of matter or any specific method of use thereof for which United States Letters Patent can be granted and includes the following or any specific method of use thereof:

"(A) any new drug, antibiotic drug, new animal drug, device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act;

"(B) any human or veterinary biological product subject to regulation under section 351 of the Public Health Service Act or under the virus, serum, toxin and analogous products provisions of the Act of Congress of March 4, 1913;

"(C) any pesticide subject to regulation under the Federal Insecticide, Fungicide, and Rodenticide Act; and

"(D) any chemical substance or mixture subject to regulation under the Toxic Substances Control Act.

"(2) The term 'major health or environmental effects test' means an experiment to determine or evaluate health or environmental effects which requires at least six months to conduct, not including any period for analysis or conclusions.

"(3) The term 'statutory use' means all uses regulated under the statutes identified in sections (c)(4)(A)-(D) for which regulatory review occurred for the product involved.

"(4) The term 'regulatory review period' means—

"(A) with respect to a food additive, color additive, new animal drug, veterinary biological product, device, new drug, antibiotic drug, or human biological product, a period commencing on the earliest of the date the patentee, his assignee, or his licensee (i) initiates a major health or environmental effects test on such product or a method for using such product (ii) claims an exemption for investigation or requests authority to prepare an experimental product with respect to such product or a method for using such product under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Act of Congress of March 4, 1913, or (iii) submits an application or petition with respect to such product or a method for using such product under such statutes, and ending on the date such application or petition with respect to such product or a method for using such product is approved or licensed under such statutes or, if objections are filed to such approval or license, ending on the date such objections are resolved and commercial marketing is permitted or, if commercial marketing is initially permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings are finally resolved and commercial marketing is permitted;

"(B) with respect to a pesticide, a period commencing on the earliest of the date the patentee, his assignee, or his licensee (i) initiates a major health or environmental effects test on such pesticide, the data from which is submitted in a request for registration of such pesticide under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act, (ii) requests the grant of an experimental use permit under section 5 of such Act, or (iii) submits an application for registration of such pesticide pursuant to section 3 of such Act, and ending on the date such pesticide is first registered, either conditionally or fully;

"(C) with respect to a chemical substance or mixture for which notification is required under section 5(a) of the Toxic Substances Control Act

"(i) which is subject to a rule requiring testing under section 4(a) of such Act, a period commencing on the date the patentee, his assignee, or his licensee has initiated the testing required in such rule and ending on the expiration of the premanufacture notification period for such chemical substance or mixture, or if an order or injunction is issued under section 5(e) or 5(f) of such Act, the date on which such order or injunction is disolved or set aside;

"(ii) which is not subject to a testing rule under section 4 of such Act, a period commencing on the earlier of the date the patentee, his assignee or his licensee—

(I) submits a premanufacture notice, or

(II) initiates a major health or environmental effects test on such substance, the data from which is included in the premanufacture notice for such substance,

and ending on the expiration of the premanufacture notification period for such substance or if an order or injunction is issued under section 5(e) or 5(f) of such Act, the date on which such order or such injunction is dissolved or set aside;

"(D) with respect to any other product or method of using a product that has been subjected to Federal premarketing regulatory review, a period commencing on the date when the patentee, his assignee or his licensee initiates actions pursuant to a Federal statute or regulation to obtain such review prior to the initial commercial marketing in interstate commerce of such product and ending on the date when such review is completed,

except that the regulatory review period shall not be deemed to have commenced until a patent has been granted for the product or the method of use of such product subject to the regulatory review period. In the event the regulatory review period has commenced prior to the effective date of this section, then the period of patent extension for such product or a method of using such product shall be measured from the effective date of this section."

Patent Term Restoration Act of 1981 (S. 255)

Explanation and Section-by-Section Analysis

The Patent Term Restoration Act of 1981 would add a new section 155 to the patent law to provide for the extension of the patent term for products and methods of using products that are subject to regulatory review pursuant to Federal statutes and regulations before they are introduced into the market for commercial use.

Section 155(a) provides that the term of a patent will be extended for a period equal to the regulatory review period for the product or method of use to which the patent applies, except that no patent term will be extended for more than seven years. The patent owner must submit a notice to the Commissioner of Patents and Trademarks, and the patent to be extended must not have expired when that notice is given.

Section 155(b) specifies the information that must be contained in the notice to the Commissioner and states that the notice must be submitted within 90 days after the regulatory review period is completed. The Commissioner is required to publish information concerning the notice and to issue the patent owner a certificate of extension.

Section 155(c) defines the terms of the Act. The definition of a "product or method for using a product" includes new drugs, antibiotic drugs, new animal drugs, devices, food additives, and color additives subject to the Federal Food, Drug, and Cosmetic Act; human and veterinary biological products; pesticides; and chemical substances and mixtures subject to the Toxic Substances Control Act.

A " major health or environmental effects test" is defined as a test that requires six months to conduct, not including time for analysis or conclusions.

"Statutory uses" are defined to mean all uses of the enumerated products and methods for using products that are regulated under applicable statutes and for which a regulatory review occurs.

A "regulatory review period" is defined in terms of the regulatory review procedures that apply to different kinds of products. For products subject to the Federal Food, Drug, and Cosmetic Act and for human and veterinary biologicals, the regulatory review period begins on the earliest of the date when a major health or environmental effects test is initiated, an investigational exemption is claimed (or an experimental permit is applied for), or an application or petition is filed. For pesticides, the review period commences when a major health or environmental effects test is begun, an experimental use permit is applied for, or a registration application is submitted. For chemical substances and mixtures subject to the Toxic Substances Control Act, the review period begins when a major health or environmental effects test is initiated pursuant to a test rule, or if no test rule applies, when a premanufacture notice is submitted or when a major health or environmental effects test is initiated for use in connection with that notice. For all products, the regulatory review period ends when a license or approval is granted or such period otherwise expires by statute. A general provision is included in section 155(c)(4)(D) to provide comparable coverage under the Act for any other product or method of using a product that is subjected to a regulatory review period pursuant to Federal statute or regulation.

The regulatory review period for a product or method of use does not commence for purposes of the Act until an applicable patent is granted. If a regulatory review period has commenced on the effective date of the Act, the period of patent extension will be measured from the effective date of the Act.●

Mr. THURMOND. Mr. President, I am pleased to join today with the distinguished Senator from Maryland (Mr. MATHIAS) in cosponsoring this legislation to amend the patent laws to restore the term of the patent that is taken up by nonpatent regulatory requirements.

In the last few years it has become painfully obvious that America's innovative capacity has been reduced substantially. In addition to backlogs in the patent application and reexamination system itself, is the added burden of regulatory requirements unrelated to the patent-seeking process. An increasing number of laws have been passed by the Congress to insure that new products are safe for the public to use. Unfortunately, the time required for this testing runs against the 17-year life of a patent. These tests are unrelated to the patent, but severely limit the time available to market the product.

This bill, Mr. President, simply restores to the life of a patent that amount of time required by Government testing of a new product. It does not restrict the Government's ability to test the safety of the product, it only gives to the patent holder the 17-year life of the patent in which to market the product once declared safe by the Government.

Mr. President, this legislation is extremely important to America's capacity to keep pace with the development of technology worldwide. The patent system is in need of reform. I ask unanimous consent that an article from U.S. News & World Report describing the condition of our present patent system be printed at the end of my remarks.

Mr. President, as chairman of the Judiciary Committee, I intend to press for early action on this measure and others that will improve this country's productivity and innovation.

There being no objection, the article was ordered to be printed in the RECORD, as follows:

PATENT SYSTEM A DRAG ON INNOVATION

(By Paul Recer)

For years, inventors have complained that federal red tape strangles ideas. Now a new administration is considering fresh approaches.

A Midwesterner spent thousands of dollars to develop a patent application and then waited five years for it to be approved. By then, the idea had been pirated by a large company. The inventor lost his investment—and the incentive to try again.

A former patent commissioner, strolling through a workroom in the U.S. Patent and Trademark Office in Arlington, Va., found a stack of patents piled on the floor in a corner, apparently misplaced or forgotten.

An inventor, after waiting for more than two years, finally received a patent report, only to discover it was in illegible handwriting.

"A cruel hoax." These incidents illustrate a development that is alarming experts: The U.S. patent process is widely regarded as so sluggish, outdated and undependable that it is contributing to the decline of innovation in America.

Millions of dollars' worth of new developments and thousands of potential jobs are tied up in registering the ownership of inventions, a system criticized as crippled by too much red tape, too little financial support, and bitter intragovernment rivalry. Says former Patent Commissioner Donald W. Banner: "A U.S. patent has become a cruel hoax, providing neither protection nor incentive for development of inventions."

The problem is of such concern to America's economic health that a blue-ribbon panel advising President Reagan devised proposals to get the system back on track. Among changes suggested: Administrative reforms, more patent examiners, computerization of files that are now only on paper and streamlining of a system basically unchanged since 1836.

A national resource of unmatched value, the Patent Office's files in Arlington include the largest depository of applied technology in the world—and the most open. Anyone may examine in minute detail those patents issued from any free country in the world.

Files include the work of such American geniuses as Thomas Edison, Samuel Morse, Cyrus McCormick and George Eastman, all of whom became famous and wealthy because U.S. patents protected their inventions.

Now, industrialists say, changes are needed to restore the patent system to its position as a help—not a hindrance—to emerging technology.

Critics says the office, with 2,700 employes and an annual budget of 112 million dollars, is understaffed, underfunded and forced to use outated office techniques. Among the problems:

Patent documents, called "prior art," are all on paper and stored in millions of boxes on shelves lining hundreds of corridors. Patent searches take weeks, with no assurance that all of the prior art is examined. Little effort has been made to develop a computerized search system for the 24 million patents on file.

Secretarial help is in such short supply that patent examiners often must file their findings in longhand.

Of the patent documents on file, at least 7 percent are actually missing—either lost, stolen or strayed. As a result, patent searches can be undependable and incomplete.

On the average, it takes 23 months for an application to be processed, and this delay is getting longer.

The value of patents, particularly for the small-time inventor, is at a low ebb. Patent rights are considered unreliable, and more than half of those tested in court have been declared invalid.

Before acting on a patent application, examiners must search all of the prior art in the appropriate classification to assure that the idea is unique. If it is, a patent is granted, and the holder theoretically is guaranteed 17 years of ownership of the idea.

The patent-search process was not a severe task when the files were small. But now, with 24 million patents filed in 100,000 subclassifications, the task can be monumental. Patent papers are stored in files and stacked in tall shelves lining block-long corridors.

Thick index books narrow the search, but each patent examiner must develop an extensive memory to keep up with his or her share of the 2,100 weekly applications.

"The whole thing is handled just like it was when Thomas Jefferson was President," says one official.

Now, the centuries-old system is breaking down, and many individuals and firms feel that getting a patent is often simply not worth the effort. Small companies find that a patent will not always protect an invention adequately. That is because some companies occasionally will risk pirating an invention when they believe a small firm can't afford a lawsuit.

Says the president of one technology company: "Stealing inventions has become an accepted business practice for big companies since they know they can probably beat the system. The little guy hardly has a chance."

In one case, a New York man who invented a digital-display system applied for a patent, but when it was granted several years later, a large company already had adopted the device. The inventor now faces years of litigation to determine who owns the idea.

NEED FOR EXAMINERS

Experts say the major difficulties at the Patent Office are that there is a shortage of examiners, and that an insufficient effort is made to keep the files updated and reclassified. New technology often is filed under old subclassifications, where it can be overlooked during patent searches.

"Even if it is there, how do you find it?" asks Michael Blommer, executive director of the American Patent Law Association. "They are so understaffed that they can't even get the antiquated system to work. And each year they're falling further and further behind."

Confidence in patent searches is further eroded by missing files. One study of the solar-energy subclassification showed that 28 percent of the prior art was gone. As a result, authors of the report said, patents granted from this subclass could be infringing on earlier, but unexamined, solar-energy patents.

"People in the marketplace are left in an uncertain status," complains Donald Dunner, a patent lawyer. "It causes dislocations in business planning. There have been some real screams of anguish."

Another problem is that patent-infringement suits have increased, overloading the courts. About 1 percent of all patents are challenged.

Patent litigation is heard first in federal district court, with appeals going to one of the 11 circuit courts of appeal. The Supreme Court seldom reviews a circuit court's findings.

"FORUM SHOPPING"

Attorneys say that some courts are known as "pro-patent" and others as "anti-patent." Thus lawyers play a vigorous game of "forum shopping," using every device to move their case to a court favorable to their cause.

Judges hearing patent cases are forced to evaluate highly technical details Observes one attorney: "The tendency is to invalidate the newer patent." Legal costs of $500,000 are not unusual in patent cases.

Reformers are also frustrated by unsuccessful efforts to make the trademark-registration system more efficient, despite expenditure of hundreds of thousands of dollars to study how to computerize the operation.

Blommer says private firms have computerized trademark files, but "the U.S. government files are all on paper. Fifty thousand applications a year, and all on paper."

Many people invloved in patent work blame the Department of Commerce for the condition of the Patent Office. Commerce controls the funds and has little interest in modernizing the operation, according to Banner.

In five of the last six years, funding has declined—when measured against inflation—while the workload has increased. Commerce officials say the PTO funding was based on an effort to use limited funds wisely.

Patent officials, however, say Commerce budget analysts, with little understanding of the patent function, annually propose only "caretaker" funds for the office.

The Department of Commerce three years ago, for example, erred on an appropriation request, and there was not enough money to pay all of the patent examiners. To avoid laying off people in a short-handed department, officials took funds from the printing budget. As a consequence, several thousand approved patents were not printed for months, holding them off the market.

Critics also are concerned that the corps of patent examiners, a group of highly skilled people regarded by many as an important national resource, has declined. There were more than 1,200 earlier in the decade, but the number dropped to abou 990 last year. At the same time, patent applications have increased, reaching a record 112,315 for 1980.

Recent attempts to change the process made little headway. At congressional hearings last year, dozens of past and present PTO officials asked for removal of the office from the Department of Commerce and establishment of an independent agency. The proposal was supported by scores of inventors, patent lawyers and company executives, but was opposed by the administration. It failed in a House committee.

But many lawyers and inventors believe the election of President Reagan and a new Congress may result in the revamping of the Patent Office after all. Reagan has indicated he intends to make it easier for innovators to get their products on the market.

SPEEDING THE PROCESS

The patent system may be helped in other ways, too. There are bills pending in Congress that would restructure the court system for faster handling of patent litigation. Laws already have been passed to streamline the issuing of licenses to permit the use of government-developed patents and to ease the re-examination of questioned patents.

Still more changes will be studied during the new term of Congress. Senator Strom Thurmond (R-S.C.), chairman of the Judiciary Committee, says changing patent laws will be one of his panel's priorities. He calls it necessary for business productivity.

Government officials point out that

changes, no matter how helpful, will not cure all the troubles of industry in introducing new technology. Still, many experts say that reforms in the patent process could fire the kind of American genius that produced so many innovations in the past.●